UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,236	03/11/2004	Abhay Sharma	U 015074-0	3561

7590 02/10/2011

Ladas & Parry
26 West 61 Street
New York, NY 10023

EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
02/10/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,236	SHARMA, ABHAY	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/22/10 has been entered.

Claims and Previous Objections/Rejections Status

2. Claims 11-15 are pending in the application.

3. The rejection of claims 11-15 under 35 U.S.C. 103(a) as being unpatentable over Sharma et al. (US 6,541,193B2) in view of Wolf et al. (*J. Neuroscience* **2002**, *22*, 11035-11044) and Faeldt et al. (US 2004/0076583A1) is maintained.

4. The new matter statement found in the advisory action 3/8/10 is withdrawn.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharma et al. (US 6,541,193B2) in view of Wolf et al. (*J. Neuroscience* **2002**, *22*, 11035-11044) and Faeldt et al. (US 2004/0076583A1).

7. Sharma et al. (US 6,541,193B2) discloses the method for screening of neuroactive drugs using the fruit fly *Drosophila melanogaster* (abstract; column 1, lines 62-64) by culturing the flies in medium under standard conditions (column 2, lines 19-20; column 3, example 1) where Sharma et al. envisioned using Oregon-R wild-type flies for the method for screening of neuroactive drugs but used Sh^5eag^1 mutant flies because they recover from ether anesthesia earlier than wild-type ones (column 2, lines 55-59). The cultured flies are separated into two groups including a first group fed with normal food and a second group fed with food mixed with an agent (phenobarbital sodium) being screened and fed for 5 days which encompasses about seven days of the instant claims (column 2, lines 23-26; column 3, example 1, especially lines 50-53). The method involves comparing flies treated with normal fly food mixed with the agent (to be screened) to flies fed on normal fly food not containing the agent (column 2, lines 23-42). In one embodiment, a blind screening of plant extracts was examine via mixing the extracts with the standard fly medium (culturing medium) in vials and transferring flies to the extract containing medium (column 4, lines 39-49). The locomotor activities of the flies fed with regular food are compared to the locomotor activities of the flies fed with food mixed with an agent where the increased locomotor activity is indicative of a psychostimulant activity of the agent (column 2, lines 39+; column 5, lines 1-10; claim 4). Sharma et al. does not disclose only one neuroactive drug, identifying the specific

locomotor activities of the instant claims or the step of measuring horizontal and vertical locomotor activities after shifting the flies to drug free media for 30 days.

8. Faeldt et al. (US 2004/0076583A1) discloses the method of screening for the effects of a test agent on a population of *Drosophila melanogaster* (including wild-type) to monitor one or more traits (i.e. locomotor activity) of the test agent, such as pilocarpine, etc. (p3, [0041-0042]; p4, [0057]; p7, [0073-0076]). Two groups or more, including a first group that are administered a test agent and a second reference group, are examined and compared for their locomotor activity (p4, [0050-0053]). The population of flies are acutely or chronically contacted with a test agent (p19, [0249]) and locomotor activity may be examined at a plurality of times during the life of the fly which encompasses measuring the various locomotor activities in flies contacted with a test agent after they have been removed from the drug containing media of the instant claim 10 (p2, [0010]; p20, [0255-0256]). The traits/locomotor activities are measured by detecting the movement of a population of flies in containers, such as in a horizontal and vertical direction (p3, [0045]; p7, [0079]-[0088]; p8, [0104]).

9. Wolf et al. (*J. Neuroscience* **2002**, *22*, 11035-11044) discloses the analysis of the locomotor activity in *Drosophila* (p11035, paragraph 3). The examination of the locomotor activity, via walking speed (fig 2) consists of alternating the exposure of air and ethanol to the flies. The flies become immobile upon overexposure to ethanol but recover when a stream of air replaces the ethanol and the hyperactive phase caused by the smell of the ethanol is attributable to internal accumulation of ethanol affecting nervous system function is indicative of neural plasticity (p11037, paragraph 1).

10. At the time of the invention it would have been obvious to one ordinarily skilled in the art to screen neuroactive drugs by monitoring the locomotor activities of wild-type *Drosophila melanogaster* as Faeldt et al. teaches the use of wild type animals for the method of screening for the effects of a test agent and Sharma et al. envisioned the use of wild-type flies for the method of screening for the effects of a test agent.

11. At the time of the invention it would have been obvious to one ordinarily skilled in the art to test the locomotor activity of a *Drosophila melanogaster* after exposure to only one neuroactive drug as Faeldt et al. teaches of the method of screening for the effects of a single test agent on a population of *Drosophila melanogaster* (including wild-type) to monitor one or more traits (i.e. locomotor activity) of the test agent (a single test agent). Thus, the *Drosophila melanogaster* are not anesthetized with ether (second neuroactive drug), as Sharma et al., prior to the examination of the locomotor activity and the examination of the locomotor activity occurs immediately after exposure to test agent.

12. Also, at the time of the invention it would have been obvious to one ordinarily skilled in the art to measure the neural plasticity resulting from the administration of a neuroactive drug for the method for screening of neuroactive drugs of Sharma et al. as Wolf et al. describes the method of administering a psychoactive drug (ethanol) to flies, monitoring the recovery from such administration, monitoring locomotor activities and thus measuring the neural plasticity. One would have a reasonable expectation of success for monitoring the neural plasticity induced by the (any) neuroactive drug once the flies have been removed from media containing a neuroactive drug since Faeldt et

al. teaches that the locomotor activity may be examined at a plurality of times during the life of the fly which encompasses measuring the various locomotor activities in flies contacted with a test agent after they have been removed from the drug containing media (Faeldt et al. p2, [0010]; p20, [0255-0256]) and the analysis of the locomotor activity in *Drosophila* allows for the effect on the nervous system function, thus neural plasticity.

Response to Arguments

13. Applicant's arguments filed 2/23/10 and 11/22/10 have been fully considered but they are not persuasive.

14. Applicant asserts that Faeldt et al. does not describe the locomotor effect of compounds used in the present invention or teach how to use these compounds.

15. The instant claims are not drawn to the method of using the neuroactive drugs.

16. The reference of Faeldt et al. was not used to teach of how to use the compounds of the disclosure but was used to teach of the method of screening for the effects of a single test agent, such as pilocarpine, etc. on a population of *Drosophila melanogaster* (including wild-type) to monitor one or more traits (i.e. locomotor activity) of the single test agent. The instant claims recite, “neuroactive drug” and the specification recites, “pilocarpine hydrochloride” (spec. p5, last paragraph). Thus, the test agent, such as pilocarpine” of Faeldt et al. encompasses the neuroactive drug of the instant claims.

17. Also, Faeldt et al. was used to teach of the examination of the locomotor activity at a plurality of times during the life of the fly which encompasses measuring the various locomotor activities in flies contacted with a single test agent after they have been removed from the drug containing media of the instant claim 10. The traits/locomotor activities are measured by detecting the movement of a population of flies in containers, such as in a horizontal and vertical direction wherein the movement traits (movement trait data) are represented by X only distance, Y only distance average X-only speed, average Y-only speed, etc. and plotted.

18. Applicant asserts that Wolf et al. teaches of short-term plasticity effect while the instant claims explicitly identify a novel Drosophila model of long-term plasticity. It is important to note here that short-term plasticity and long-term plasticity represent two different biological phenomena. Existence of short-term plasticity model does not make it obvious that a long-term plasticity model can be derived using the knowledge. In addition, a compound could not have an effect on short or long term plasticity, both or neither. Further, drug screening models based on short-term plasticity will be different from those based on long-term plasticity in terms of usefulness.

19. The reference of Wolf et al. was not used to teach of long-term plasticity but was used to teach that the examination of the locomotor activity of drugs affecting nervous system function is indicative of neural plasticity.

20. The reference of Faeldt et al. was used to teach of the examination of the locomotor activity at a plurality of times during the life of the fly (e.g. long term) which encompasses measuring the various locomotor activities in flies contacted with a test

agent after they have been removed from the drug containing media of the instant claim 10. The traits/locomotor activities are measured by detecting the movement of a population of flies in containers, such as in a horizontal and vertical direction wherein the movement traits (movement trait data) are represented by X only distance, Y only distance average X-only speed, average Y-only speed, etc. and plotted. Thus, the long-term effects, such as neural plasticity are examined over a period of time during the life of the fly, such as long-term over the life-span of the fly.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618